THERAFLU MULTI-SYMPTOM SEVERE COLD AND THERAFLU NIGHTTIME SEVERE COLD AND COUGH- acetaminophen, dextromethorphan hbr, phenylephrine hcl, diphenhydramine hcl
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Theraflu Multi-Symptom Severe Cold

Active ingredients (in each packet)

Acetaminophen 500 mg

Dextromethorphan HBr 20 mg

Phenylephrine HCl 10 mg

Purposes

Pain Reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold:
    - minor aches and pains
    - minor sore throat pain
    - headache
    - nasal and sinus congestion
    - cough due to minor throat and bronchial irritation
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting consult a doctor promptly.

Do not use

- in a child under 12 years of age
- if you are allergic to acetaminophen
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma or emphysema

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin

When using this product

- **do not exceed recommended dosage**

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not use more than directed**
- take every 4 hours, while symptoms persist. Do not take more than 6 packets in 24 hours unless directed by a doctor.

Age	Dose
adults and children 12 years of age and over	one packet
children under 12 years of age	do not use

- dissolve contents of one packet into 8 oz. hot water; sip while hot. Consume entire drink within 10-15 minutes.
- if using a microwave, add contents of one packet to 8 oz. of cool water; stir briskly before and after heating. Do not overheat.

Other information

- **each packet contains:** potassium 10 mg, sodium 19 mg
- **phenylketonurics:** contains phenylalanine 20 mg per packet
- store at controlled room temperature 20°-25°C (68°-77°F). Protect product from heat and moisture.

Inactive ingredients

acesulfame potassium, anhydrous citric acid, aspartame, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, flavors, maltodextrin, silicon dioxide, sodium citrate, sucrose, tribasic calcium phosphate

Questions or comments?

call **1-855-328-5259**

Theraflu Nighttime Severe Cold & Cough

Active ingredients (in each packet)

Acetaminophen 650 mg

Diphenhydramine HCl 25 mg

Phenylephrine HCl 10 mg

Purposes

Pain reliever/fever reducer

Antihistamine/cough suppressant

Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold:
    - minor aches and pains
    - minor sore throat pain
    - headache
    - nasal and sinus congestion
    - runny nose
    - sneezing
    - itchy nose or throat
    - itchy, watery eyes due to hay fever
    - cough due to minor throat and bronchial irritation
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by

fever, headache, rash, nausea, or vomiting consult a doctor promptly.

Do not use

- in a child under 12 years of age
- if you are allergic to acetaminophen
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other product containing diphenhydramine, even one used on the skin
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma or emphysema

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

- **do not exceed recommended dosage**
- avoid alcoholic drinks
- marked drowsiness may occur
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not use more than directed**
- take every 4 hours, while symptoms persist. Do not take more than 5 packets in 24 hours unless directed by a doctor.

Age	Dose
adults and children 12 years of age and over	one packet
children under 12 years of age	do not use

- dissolve contents of one packet into 8 oz. hot water; sip while hot. Consume entire drink within 10-15 minutes.
- if using a microwave, add contents of one packet to 8 oz. of cool water; stir briskly before and after heating. Do not overheat.

Other information

- **each packet contains:** potassium 10 mg, sodium 23 mg
- **phenylketonurics:** contains phenylalanine 13 mg per packet
- store at controlled room temperature 20°-25°C (68°-77°F). Protect product from heat and moisture.

Inactive ingredients

acesulfame potassium, anhydrous citric acid, aspartame, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, flavors, maltodextrin, silicon dioxide, sodium citrate, sucrose, tribasic calcium phosphate

Questions or comments?

call **1-855-328-5259**

Additional Information

DO NOT TAKE THE MULTI-SYMPTOM AND NIGHTTIME PRODUCTS AT THE SAME TIME. DO NOT TAKE MORE THAN 5 DOSES IN TOTAL IN ANY 24 HOUR PERIOD.

PARENTS: Learn about teen medicine abuse

www.StopMedicineAbuse.org

TAMPER-EVIDENT INNER UNIT.

DO NOT USE IF SEALED THERAFLU PACKET IS TORN OR BROKEN.

1-855-328-5259

Distributed by: **GSK Consumer Healthcare,** Warren, NJ 07059

READ ALL WARNINGS AND DIRECTIONS ON CARTON BEFORE USE.

KEEP CARTON FOR REFERENCE. DO NOT DISCARD.

DO NOT TAKE THE MULTI-SYMPTOM AND NIGHTTIME PRODUCTS AT THE SAME TIME. DO NOT TAKE MORE THAN 5 DOSES IN TOTAL IN ANY 24 HOUR PERIOD.

DO NOT TAKE A DOSE OF THE NIGHTTIME PRODUCT SOONER THAN 4 HOURS AFTER THE LAST DOSE OF MULTI-SYMPTOM PRODUCT UNLESS DIRECTED BY YOUR DOCTOR.

Principal Display Panel

NDC 0067-7919-12

THERAFLU

MULTI-SYMPTOM SEVERE COLD

Acetaminophen

Pain Reliever/Fever Reducer

Dextromethorphan HBr

Cough Suppressant

Phenylephrine HCl

Nasal Decongestant

- ***Cough***
- ***Nasal Congestion***
- ***Sore Throat Pain***
- ***Headache***
- ***Body Ache***
- ***Fever***

TEA INFUSIONS

GREEN TEA & HONEY LEMON FLAVORS

MULTI-SYMPTOM 6 PACKETS

NIGHTTIME

SEVERE COLD & COUGH

Acetaminophen

Pain Reliever/Fever Reducer

Diphenhydramine HCl

Antihistamine/Cough Suppressant

Phenylephrine HCl

Nasal Decongestant

- ***Cough***
- ***Nasal Congestion***
- ***Sore Throat Pain***
- ***Headache***
- ***Body Ache***
- ***Fever***
- ***Runny Nose***
- ***Sneezing***

HONEY LEMON INFUSED WITH CHAMOMILE & WHITE TEA FLAVORS

NIGHTTIME 6 PACKETS

USE AS DIRECTED

12 TOTAL PACKETS

gsk

13469

Principal Display Panel

NDC 0067-8200-01

THERAFLU

MULTI-SYMPTOM SEVERE COLD

Acetaminophen

Pain Reliever/Fever Reducer

Dextromethorphan HBr

Cough Suppressant

Phenylephrine HCl

Nasal Decongestant

- ***Cough***
- ***Nasal Congestion***
- ***Sore Throat Pain***
- ***Headache***
- ***Body Ache***
- ***Fever***

TEA INFUSIONS

GREEN TEA & HONEY LEMON FLAVORS

MULTI-SYMPTOM 18 PACKETS

NIGHTTIME

SEVERE COLD & COUGH

Acetaminophen

Pain Reliever/Fever Reducer

Diphenhydramine HCl

Antihistamine/Cough Suppressant

Phenylephrine HCl

Nasal Decongestant

- ***Cough***
- ***Nasal Congestion***
- ***Sore Throat Pain***
- ***Headache***
- ***Body Ache***
- ***Fever***
- ***Runny Nose***
- ***Sneezing***

HONEY LEMON INFUSED WITH CHAMOMILE & WHITE TEA FLAVORS

NIGHTTIME 6 PACKETS

USE AS DIRECTED

24 TOTAL PACKETS

gsk

13471

THERAFLU MULTI-SYMPTOM SEVERE COLD AND THERAFLU NIGHTTIME SEVERE COLD AND COUGH

acetaminophen, dextromethorphan hbr, phenylephrine hcl, diphenhydramine hcl kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0067-7919

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-7919-12	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	01/01/2016	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	6 PACKET	1422 mL
Part 2	6 PACKET	1422 mL

Part 1 of 2

THERAFLU MULTI-SYMPTOM SEVERE COLD

acetaminophen, dextromethorphan hbr, phenylephrine hcl powder, for solution

Product Information

Item Code (Source)	NDC:0067-6426
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg in 237 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 237 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 237 mL

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	HONEY (GREEN TEA & HONEY LEMON FLAVORS)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-6426-06	6 in 1 CARTON		
1	NDC:0067-6426-01	237 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2014	

Part 2 of 2

THERAFLU NIGHTTIME SEVERE COLD AND COUGH

acetaminophen, diphenhydramine hcl, phenylephrine hcl powder, for solution

Product Information

Item Code (Source)	NDC:0067-7918
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 237 mL
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 237 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 237 mL

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	HONEY, LEMON (HONEY LEMON INFUSED WITH CHAMOMILE & WHITE TEA FLAVORS)	**Imprint Code**	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-7918-06	6 in 1 CARTON		
1	NDC:0067-7918-01	237 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2014	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/01/2016	

THERAFLU MULTI-SYMPTOM SEVERE COLD AND THERAFLU NIGHTTIME SEVERE COLD AND COUGH

acetaminophen, dextromethorphan hbr, phenylephrine hcl, diphenhydramine hcl kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0067-8200

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-8200-01	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	09/01/2019	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	18 PACKET	4266 mL
Part 2	6 PACKET	1422 mL

Part 1 of 2

THERAFLU MULTI-SYMPTOM SEVERE COLD

acetaminophen, dextromethorphan hbr, phenylephrine hcl powder, for solution

Product Information	
Item Code (Source)	NDC:0067-6426
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg in 237 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 237 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 237 mL

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	HONEY (GREEN TEA & HONEY LEMON FLAVORS)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-6426-06	6 in 1 CARTON		
1	NDC:0067-6426-01	237 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2014	

Part 2 of 2

THERAFLU NIGHTTIME SEVERE COLD AND COUGH

acetaminophen, diphenhydramine hcl, phenylephrine hcl powder, for solution

Product Information

Item Code (Source)	NDC:0067-7918
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 237 mL
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 237 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 237 mL

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	HONEY, LEMON (HONEY LEMON INFUSED WITH CHAMOMILE & WHITE TEA FLAVORS)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-7918-06	6 in 1 CARTON		
1	NDC:0067-7918-01	237 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/01/2016	

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Revised: 8/2021

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC